§ 12.18 Labels.

Each separate container of such virus, serum, toxin, or analogous product imported is required by the regulations of the Department of Agriculture to bear the true name of the product and the permit number assigned by the Department of Agriculture in the following form: ''U.S. Veterinary Permit No. _____,'' or an abbreviation thereof authorized by the Animal and Plant Health Inspection Service, Veterinary Services. Each separate container also shall bear a serial number affixed by the manufacturer for identification of the product with the records of preparation thereof, together with a return date.

[28 FR 14710, Dec. 31, 1963, as amended by T.D. 78–99, 43 FR 13060, Mar. 29, 1978]

§ 12.19 Detention; samples.

(a) The port director shall detain all shipments of such products for which no permit to import has been issued pending instructions from the Department of Agriculture.

(b) Samples shall be furnished to the Department of Agriculture upon its request, and the port director shall immediately notify the consignee of any such request.

§ 12.20 Disposition.

Viruses, serums, or toxins rejected by the Department of Agriculture shall be released by the port director to that Department for destruction, or exported under Customs supervision at the expense of the importer if exportation is authorized by the Department of Agriculture.

VIRUSES, SERUMS, TOXINS, ANTITOXINS, AND ANALOGOUS PRODUCTS FOR THE TREATMENT OF MAN

§ 12.21 Licensed establishments.

The bringing into the United States for sale, barter, or exchange, of any virus, therapeutic serum, toxin, antitoxin, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man is prohibited unless such virus, serum, toxin, antitoxin, or other product has been manufactured at an establishment holding an unsuspended and unrevoked license issued by the Secretary of Health and Human Services for such manufacture.

[T.D. 69–201, 34 FR 14328, Sept. 12, 1969, as amended by T.D. 82–145, 47 FR 35476, Aug. 16, 1982]

§ 12.22 Labels; samples.

Each package of such products imported for sale, barter, or exchange shall be labeled or plainly marked with the name, address, and license number of the manufacturer, and the date beyond which the contents cannot be expected to yield their specific results. From each lot of product the port director shall select at random at least two final containers. The random sample together with a copy of the associated documents which describe and identify the shipment shall be forwarded to the Director, Bureau of Biologics, Food and Drug Administration, 8800 Rockville Pike, Bethesda, Md. 20014. For shipments of 20 or less final containers, samples need not be forwarded, provided a copy of an official release from the Bureau of Biologics accompanies each shipment.

[T.D. 69–201, 34 FR 14328, Sept. 12, 1969, as amended by T.D. 82–145, 47 FR 35476, Aug. 16, 1982]

§ 12.23 Detention; examination; disposition.

(a) Port directors shall detain all importations of unlicensed viruses, therapeutic serums, toxins, antitoxins, and analogous products, and arsphenamines or its derivatives (or any other trivalent organic arsenic compound) for the treatment or cure of diseases or injuries of man pending examination by the Director, Bureau of Biologics, unless satisfied from evidence furnished at the time of entry that the products are intended solely for purposes of controlled investigation and not for sale, barter, or exchange, as evidenced by a copy of a filed ''Notice of Claimed Investigational Exemption for a New Drug,'' pursuant to §312.1 of the Food, Drug, and Cosmetic Act Regulations (21 CFR 312.1), or are being imported under the short supply provisions of §601.22 of the Public Health Service Regulations (42 CFR 601.22).